

DEPARTMENT OF HEALTH AND HUMAN SERVICES

JUN 7 1996

Ms. Susan C. MacIntosh
Regulatory Affairs Manager
Plant Genetic Systems (America) Inc.
7200 Hickman Road
Des Moines, Iowa 50322

Dear Ms. MacIntosh:

This is in regard to Plant Genetic System's (PGS's) consultation with the Food and Drug Administration (FDA) (Center for Veterinary Medicine (CVM) and Center for Food Safety and Applied Nutrition (CFSAN)) on genetically modified corn, specifically, transformation event MS3 and progeny derived therefrom. According to PGS, the new corn variety has been modified for male sterility through anther-specific expression of the *barnase* gene derived from *Bacillus amyloliquefaciens*.

On February 25, 1994, representatives of PGS met with representatives of CVM and CFSAN to discuss the safety assessment of male sterile corn. In a letter dated January 12, 1996, PGS submitted a summary assessment of the food and feed wholesomeness of corn containing transformation event MS3 and progeny derived therefrom.

These communications informed FDA of the steps taken by PGS to ensure that corn derived from transformation event MS3 complies with the legal and regulatory requirements that fall within FDA's jurisdiction. Based on the safety and nutritional assessment that PGS has conducted, it is our understanding that PGS has concluded that corn grain and silage derived from the new variety are not materially different in composition, safety, and other relevant parameters from corn grain and silage currently on the market and that the genetically modified corn does not raise issues that would require premarket review or approval by FDA. All materials relevant to this notification have been placed in a file designated BNF0031. This file will be maintained in the Office of Premarket Approval in CFSAN.

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Based on the information PGS has presented, we have no further questions concerning corn grain and silage derived from transformation event MS3 at this time. However, as you are aware, it is PGS's continued responsibility to ensure that foods marketed by the firm are safe, wholesome and in compliance with all applicable legal and regulatory requirements.

Sincerely yours,

/s/

Alan M. Rulis, Ph.D.
Director
Office of Premarket Approval
Center for Food Safety
and Applied Nutrition

cc:	HFS-200	HFS-205	HFS-226	HFS-235	HFS-246	HFS-247
	HFS-13	HFS-144	HFV-200	HFV-221	HFV-224	HFV-225
	HFS-206					